iGEM IISER Thiruvananthapuram x iGEM IISER Tirupati

Legal Landscape of Biotechnology in India

A Handbook on Biotechnology Laws in India and Multilateral Agreements

PREFACE

This handbook was drafted by the iGEM teams of IISER Thiruvananthapuram and IISER Tirupati as a collaboration project as part of Human Practices for the iGEM Competition.

The handbook is intended to promote responsible research by scientists researching synthetic biology. The book compiles relevant biotechnology laws in India and multilateral legal agreements of which India is a part and seeks to identify and explore the legal gaps and unattended problems. The book's objective is to inform the researchers of the biotechnology laws that they have to go through before starting research activity. The biotechnology laws are scattered throughout the constitution and are governed by several enactments depending on case to case basis. This book attempts to capture the multiple facets of laws that must be abided by while performing scientific experiments in biotechnology.

Moreover, the book can also be of use to Indian iGEM teams in the future and can be treated as a beginners' guide to the legal scenario pertaining to biotechnology in India.

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CHAPTER 1
ANIMAL EXPERIMENTATION AND CLINICAL TRIALS

Animal testing, also known as animal experimentation, animal research, and in vivo testing, refers to the scientific study of non-human animals, usually in a laboratory, for the purpose of gaining new biological knowledge or solving specific medical, veterinary medical, dental, or biological problems. Animal experimentation is also a significant part of a larger section of biological research in the country.

iGEM, being an international synthetic biology competition also has the involvement of animal research in many sections of research work undertaken by various teams. This chapter of the book would provide a brief overview of existing laws and regulations in India that relates to animal experimentation and clinical trials, and also a few things that an iGEM team working on animal models should have in mind.

The relevant legal provisions discussed in this chapter include:

1. Prevention of Cruelty to Animals Act, 1960
2. Breeding of Experiments on Animals (Control and Supervision) Rules, 1998
3. Drug and Cosmetics Act, 1940
4. Right to Information Act, 2005
5. Guidelines for generating pre-clinical data for rDNA vaccines, diagnostics and other biologicals

1. Prevention of Cruelty to Animals Act, 1960

The Prevention of Cruelty to Animals Act was ratified in 1960 to prevent the infliction of unnecessary pain or suffering in animals and to amend the laws relating to the prevention of cruelty to animals. It was authored and acclaimed by dancer and animal lover Rukmini Devi Arundale. This act also led to the formation of the Animal Welfare Board of India.

According to the act, any living creature other than a human is referred to as an animal. And, it is the duty of every person having the care or charge of any animal to take all rational measures to ensure the well-being of such animals and to prevent the infliction of unnecessary pain or suffering on such animals.

Cruelty to animals, in general, can take many forms which include physical torture (beat, kick, over-ride, over-work, starvation), administering injurious drugs, etc. The punishments for these cruelties range from fines with not less than Rs.10 to Rs.100 and imprisonment.

Researchers planning to work/experiment on animals should go through Chapter IV of this act, which clearly lists out the prerequisites before starting to do so.

2. Breeding of Experiments on Animals (Control and Supervision) Rules, 1998

The committee for control and supervision of animals made these rules under the Prevention of Cruelty to Animals Act, 1960. This set of rules mandates the need for an Institutional Animal Ethics Committee (IAEC) for any establishment that is engaged in any sort of animal breeding for research purposes. The IAEC members are scientists, veterinarians both from inside and outside the institute. Every registered establishment before acquiring an animal or conducting any experiment on animal(s) shall apply for permission of the IAEC.

3. Drug and Cosmetics Act, 1940

Initially called the Drug Act, this legislation was passed in 1940 as per recommendations of the Chopra Committee which was formed to build a comprehensive legislation for regulating the import of drugs to the country. It has since then undergone several amendments and is currently known as the Drugs and Cosmetics Act, 1940, which regulates the import, manufacture and distribution of drugs in India. The act primarily focuses to ensure that the drugs and cosmetics sold in India are safe, effective and conform to proper quality standards.

According to the act, the term "drug" includes a wide variety of substances, diagnostics and medical devices. The Drug and Cosmetics Rules, 1945 was established through this act and has strict and elaborate guidelines to be followed during the different phases of clinical trials.

4. Right to Information Act, 2005

The Right to Information (RTI) is an act of the Indian Parliament that sets out the procedures and rules regarding citizens' right to information. It was a replacement to the former Freedom of Information Act, 2002.

Under the provisions of the RTI Act, any citizen of India may request information from a "public authority" which is required to reply within thirty days. With a view to protecting patient-related information and preserving exclusive intellectual property rights of the pharmaceutical companies, the Central Information Commission (CIC) recently passed a decision acknowledging exemption from disclosure of information on clinical trials under the Right to Information (RTI) Act, 2005. CIC while passing its decision said that transparency is an essentiality in biomedical research. Nevertheless, such information

should not be disclosed to the public as it includes several strategic and scientific data along with patient-related information.

5. Guidelines for generating pre-clinical data for rDNA vaccines, diagnostics and other biologicals

Biotechnology is known for social and economic progress in developed and developing countries. Biotechnology research and its applications especially in the pharmaceutical and healthcare sectors also growing at a rapid rate. Products and processes developed through rDNA technology are already available for the public. More and more such products will become available very soon. Therefore, regulatory standards for recombinant (rDNA) products are essential. There is a need to formulate appropriate guidelines for preclinical and clinical evaluations in our country. These guidelines specifically are on the safety, purity, potency and effectiveness of an rDNA product.

What should you take care of as an iGEM team?

iGEM being an international synthetic biology competition has numerous teams using animal models in their research. Different parts of the world have different governance measures for the oversight of the use of animals in research. Relevant values are not universal and regulatory oversight measures may not be present. Moreover, when considering the use of animals in iGEM projects, teams should reflect on three core principles:

1. **Replace** – whenever possible alternatives to animal models should be used. Teams must be ready to explain why no alternative approaches were possible.
2. **Reduce** – if animals are to be used, the fewest possible needed to accomplish the goal of the research should be used.
3. **Refine** – animal use must be for a specific purpose and the rationale behind their use, the protocols to be used, and how that use will further scientific knowledge all need careful consideration. Animal welfare must also be given due consideration.

Teams planning to work on any multicellular organisms (animals, plants, insects, etc.) not on the White List require permission from the Safety and Security Committee. Teams are required to complete a check-in form mentioning any potential risks associated with their work and how they will be managing them.

Teams using vertebrates or higher-order invertebrates should also submit an Animal Use form in addition to their Safety Check-In Form. Furthermore, all animal research must comply with their parent institute’s and the country’s ethical policies and guidelines.

In addition to iGEM's policies, teams are required to receive approval from the IAEC and the IBSC before commencing research on animals. However, work on *Drosophila* does not require approval from the IAEC.

CHAPTER 2
IMPORT AND EXPORT

Foreign trade is an inevitable factor for the overall economic development of a country. Ministry of Commerce and Industry, Office of Directorate General of Foreign Trade, Ministry of Finance, Draw Back Directorate, Export Inspection Council, etc., are the central departments that deal with foreign trade in India. EXIM Policy is a set of guidelines established by DGFT (Directorate General Of Foreign Trade) in importing and exporting goods in India. Foreign Trade Development and Regulation Act, 1992 mainly regulates the EXIM policy of India.

The import, export, and exchange (within the country) of Genetically Engineered (GE) organisms, non-GE hazardous microorganisms and products thereof, and vectors of disease or their carriers are subject to approval from competent regulatory authorities. Depending on the purpose, IBSC, RCGM, or GEAC shall issue relevant permits for such activities.

The relevant legal provisions discussed in this chapter include:

1. Foreign Trade Policy for import of GM Products, 2006
2. SCOMET List
3. Rules for the manufacture, use/import/export, and storage of hazardous microorganisms/genetically engineered organisms or cells, 1989
4. Biological Diversity Act, 2002
5. Standard Operating Procedure for the transport of regulated genetically engineered plant material
6. Plant Quarantine (Regulation of import into India) Order, 2003

1. Foreign Trade Policy for Import of GM Products, 2006

The import of GMOs/LMOs for research and development, food, feed, processing in bulk, and environment release is governed by the provisions of the Environment Protection Act, 1986 and rules 1989. The import of any food product that contains GM material and is being used either for environmental release, industrial production, or field application will be allowed only with the approval of the Genetic Engineering Approval Committee (GEAC). Institutes who wish to import Genetically Modified material for R & D purposes have to submit their proposal to the RCGM. In case the institutes use this GM material for commercial purposes, approval of GEAC is also required. At the time of import, all consignments containing products that have been subjected to genetic modification have

to carry a declaration stating that the product is genetically modified. If the consignment does not carry the above-mentioned declaration and is later found to contain genetically modified material, the importer is liable to penal action under the Foreign Trade (Development and Regulation) Act, 1992.

2. SCOMET List

SCOMET stands for Special Chemicals, Organisms, Materials, Equipment, and technologies. It governs the export of dual-use items from India and objects to certain sensitive items not falling into the hands of terrorists, non-state actors, or terrorists. The SCOMET list was notified under Section 5 and Section 14A of the Foreign Trade (Development & Regulation) Act ('FTDR' Act) of 1992, providing India's international trade regulation and development.

The Foreign Trade Policy of India ('FTP') governs India's export and import of goods. The import and export of goods and services are free unless expressly prohibited or regulated or subject to exclusive trading through the State Trading Enterprises. In such an unrestricted international trade scenario, there is a regulated list of items called the SCOMET list.

Dual-use items are primarily technologies, organisms, chemicals, and goods that can potentially have both civil and military applications and could be deployed as weapons of mass destruction.

3. Rules for the Manufacture, Use/Import/Export, and Storage of Hazardous Microorganisms/Genetically Engineered Organisms or Cells, 1989

'Rules for the Manufacture, Use/Import/Export, and Storage of Hazardous Microorganisms/Genetically Engineered Organisms or Cells, 1989' notified under the Environmental Protection Act, 1986, provides the regulatory framework for various activities involving GMOs. This set of rules were notified as per powers conferred by sections 'Regulation of Genome Engineering Technologies in India,' 8 and 25 of Environment (Protection) Act, 1986. The rules are broad and designed to include a wide spectrum of activities involving GMOs and parts thereof, including their use, production and manufacture, import, export, storage, and sale. These rules are implemented by the Ministry of Environment, Forest and Climate Change, Department of Biotechnology, and State Governments through six competent authorities.

The act requires a person to receive approval from the Genetic Engineering Approval Committee (GEAC) to import, export, transport, manufacture, process, use or sell any

hazardous microorganism or genetically engineered organism or substances. It also specifies that the use of pathogenic organisms or genetically engineered organisms or cells for research purposes shall be only permitted in laboratories and laboratory premises. If the study conducted within the field of gene technology or microorganisms requires the researcher to perform experiments outside of the laboratory or laboratory premises, the law requires you to obtain permission from the Institutional Biosafety Committee. The law further prohibits the release of genetically engineered organisms or hazardous microorganisms or cells, either deliberate or accidental, including the deliberate release for research. Under exceptional circumstances, however, the deliberate release may be permitted with the approval of the Genetic Engineering Approval Committee. It is also to be noted that the approval granted by GEAC is valid only for a specified period, not more than four years. The law further states that GEAC has the power to revoke the approval if there is any new information on the harmful effects of genetically engineered organisms or cells or if their release results in damage to the environment, health, or nature, which could not be predicted when the approval was granted. The law also prohibits the discharge of GMOs and hazardous microorganisms. In instances of such occurrences, if the GMO is perceived to pose a risk to health or environmental safety, the person is required to immediately notify the State Biotechnology Coordination Committee, the state medical officer. Further, the person responsible shall also be required to provide any necessary information to make the off-site emergency plan.

4. Biological Diversity Act, 2002

Export and import of GMOs would also attract the provisions of the Biological Diversity Act, 2002 related to the access and use of biological resources. A person who is not a citizen of India or a citizen of India, who is a non-resident or a body corporate, association or organization that is not incorporated or registered in India or incorporated or registered in India under any law for the time being in force which has any non-Indian participation in its share capital or management is required to have approval from National Biodiversity Authority to obtain any biological resource occurring in India or knowledge associated thereto for research or commercial utilization or bio-survey and bio-utilization.

5. Standard Operating Procedure (SOP) for the Transport of Regulated Genetically Engineered Plant Material

This SOP regulates genetically engineered seed or propagable plant material for import, export, interstate movement, and intra-state movement. All regulated, genetically engineered seed or propagable plant material must be stored in secure containers/packets for transportation, must be kept separate from other plant materials during transport, clearly labelled. The Permitted Party will ensure that appropriate

containers/packaging materials are supplied to all agents working on their behalf to transport regulated, genetically engineered seed or propagable plant material.

6. Plant Quarantine (Regulation of Import into India) Order, 2003

This order was enacted to prohibit and regulate the import into India of agricultural articles.

No consignment of germplasm/transgenics/genetically modified organisms (GMOs) shall be imported into India for research/experimental purposes without a valid permit issued by the Director, National Bureau of Plant Genetic Resources. Here, "purpose of agricultural research or the purpose of experimentation" will not include commercial imports, which are governed by separate guidelines issued by the GEAC, or as the case may be, by the RCGM. No imported consignments of plant germplasm/ transgenics/ genetically modified pests can be opened at the point of entry, and they shall be forwarded to the Director, National Bureau of Plant Genetic Resources.

What should you take care of as an iGEM team?

Since most iGEM teams require to work with gene fragments in some part of their project, they will have a hustle while importing them from abroad. Ensure to consult with the 'purchase department' of your institute during the purchasing or importing of any reagents/chemicals from outside.

CHAPTER 3
HUMAN AND ENVIRONMENTAL SAFETY

Genetic engineering is a field of growing importance that can potentially offer solutions to countless problems. While the future of Genetic engineering looks promising and optimistic, its unregulated use can negatively impact Human and Environmental Safety. The usage of GMOs needs to be well studied and regulated to prevent human health risks such as pathogenicity or toxicity. The release of Genetically modified organisms (GMOs) into the natural environment poses several ecological risks, which include genetic contamination, horizontal transfer of recombinant genes, and other impacts on the ecosystem. The fast-paced advances in gene technologies also raise the question of bioterrorism and biosafety. Taking into account these health safety and ecological considerations, India has established a structured and systematic framework for the regulation of Genetic Engineering. India is also a signatory to multilateral legal agreements like the Convention of Biological Diversity (CBD), Cartagena Protocol, and Nagoya Protocol which aims to improve the accessibility of genetic resources, fair and equitable sharing of genetic resources, and biosafety.

It is imperative that Researchers understand the current regulations on Genetic Engineering, Environmental laws and Biocontainment laws governing scientific research while designing scientific studies or experiments to ensure safety and security. This chapter discusses the handling of genetically engineered organisms, management of biomedical waste, and conservation of biodiversity.

The researchers are required to abide by these laws while conducting their research, and non-compliance can result in imprisonment and a fine depending on the gravity of the issue. Further, understanding the existing legislation would allow researchers to influence policy-making by recognising potential risks and providing evidence to enable policymakers to make informed decisions.

The relevant legal provisions discussed in this chapter include:

1. Environment Protection Act, 1989
2. Biomedical Waste (Management and Handling) Rules, 1998
3. Biological Diversity Act

1. Environment Protection Act, 1989

Environmental Protection Act (EPA), 1989 was introduced by the Ministry of Environment, Forest, and Climate Change to provide a legal framework for ensuring the protection of the environment and prevention and/or reduction of environmental pollution. The act formulated includes rules with regard to regulation of environmental pollution, handling of hazardous substances. EPA was enacted following the Bhopal Gas Tragedy under Article 253 of the Indian Constitution, the aftermath of the tragedy made the government realize that the existing laws were not enough and recognized the need for umbrella legislation to deal with environmental issues. Following the installation of the Environmental Protection Act, a series of Rules were notified to address various problems such as hazardous chemicals, hazardous wastes, solid wastes, biomedical wastes, etc. The usage of microorganisms and application of gene technology is further regulated by “Rules for manufacture, use/import/export & storage of hazardous microorganisms/genetically engineered organisms or cells, 1989” notified under EPA, which is included in the next section of this handbook.

The act takes a precautionary approach to prevent the occurrence of accidents that can have an environmental impact. It emphasises the safe handling of hazardous substances and requires a person to mandatorily comply with safety protocols prescribed. The Act also prescribes that in the event of discharge of environmental pollutants higher than the prescribed standards the person or the agency responsible is required to intimate the fact of such occurrence to concerned authorities and is bound to provide all assistance for implementing remedial measures. The law also holds the person liable to pay for the expenses incurred by any authorities together with interest. Failure to comply with the rules under this Act is punishable by imprisonment of up to five years and a fine that may extend to 5 lakh rupees.

2. Biomedical Waste (Management and Handling) Rules, 1998

The Biomedical Waste (Management and Handling) Rules, 1998 was notified under the Environmental Protection Act and came into force in 1998. The rule was notified under the Environmental Protection Act for the management of biomedical waste generated from hospitals, clinics, and other institutions for scientific management of Biomedical waste as per powers conferred under Sections 6, 8, and 25.

The rule prescribes the regulatory framework for segregation, transportation, packaging, and storage. The Rule recognises the safe handling and transportation of biomedical waste without posing any harm to human and environmental safety as the duty of the

operator. The law stipulates that the operator is liable to make provision for the safe handling and storage of biomedical waste and bars any secondary handling and inadvertent scattering or spillage. The rule also prohibits the mixing of the waste prior to disposal and should be segregated as per relevant protocols and regulations. The law also prescribes the institutions, hospitals or any agency that may be handling Biomedical waste, to ensure the disposal of laboratory waste, microbiological waste, blood samples, and blood bags through disinfection or sterilisation on-site as prescribed by the World Health Organisation (WHO) or National AIDs Control Organisation (NACO) guidelines before sending to the common bio-medical waste treatment facility for final disposal. The law further requires the institutions to establish a Bar- Code System for bags or containers containing bio-medical waste to be sent out of the premises or place. Violating the provisions of this Act can lead to imprisonment that may extend to 5 years with a fine. The Board can also have directions for closure of any defaulting hospital/clinic/institution under section 5 of EP Act as per powers delegated by the Central Govt.

3. Biological Diversity Act, 2002

The Biological Diversity Act, 2002 seeks to preserve biological diversity in India. It provides a mechanism for equitable sharing of benefits arising out of the use of traditional biological resources and knowledge. The Act was adopted as an obligation under the Convention on Biological Diversity, as India is a party in the convention. The offences conducted under this Act are cognizable and non-bailable. Non-compliance to the Act is punishable by imprisonment that may extend to five years and a fine of up to ten lakh rupees.

The law bars any person who is not an Indian citizen or a non-resident Indian citizen or an on the organization not registered in India or has any non-Indian participation in its share capital or management from obtaining any biological resource occurring in India or any knowledge associated with research or commercial activities including bio survey and bio utilisation. For these people to conduct biodiversity-related activities a prior approval from the National Biodiversity Authority is required. The law also restricts the transfer of results of any research relating to any biological resources occurring in, or obtained from, India in exchange for money or otherwise to any person who is not an Indian citizen or a non-resident Indian citizen or an on the organization not registered in India or has any non-Indian participation in its share capital or management. But it may be noted that publication of research papers or dissemination of knowledge in any seminar or workshop is exempted from being subjected to the regulation if the publication is in accordance with the guidelines issued by the Central Government. The law also requires a person to obtain prior permission from National Biodiversity Authority to apply for any intellectual property rights in or outside India to for any invention based on any research or information on a biological resource obtained from India. The offences conducted

under this Act are cognizable and non-bailable. Non-compliance to the Act is punishable by imprisonment that may extend to five years and a fine of up to ten lakh rupees.

What should you take care of as an iGEM team?

Being a synthetic biology competition, all iGEM projects carry a certain risk factor in their execution and implementation. All teams are required to identify and manage any form of risks involved in their project. This has to be conveyed to the Safety and Security Committee of iGEM by the submission of a Safety Check-In form.

All team members are required to undergo rigorous training and have a proper insight into basic laboratory protocols (including waste management). They should also be aware of each chemical and equipment they use. Teams can also incorporate kill switches (or any other genetic circuits) to ensure no accidental release of their GMOs in the environment. Thorough knowledge about different risk groups of the organisms involved in the project would aid the teams in filling up the check-in form.

Specifically, Indian teams must receive approval from their Institutional Biosafety Committee (IBSC) before their laboratory work starts. IBSC would then forward the proposal to the Review Committee on Genetic Manipulations (RCGM)- a central government authority that would approve our project later.

In addition to safe laboratory practices, all non-invasive experiments (eg.: surveys) involving human subjects should have approval from the Research Ethics Committee of the parent institution. The absence of such a committee in several Indian institutes would mean acquiring thorough review and approval from the PIs and relevant authorities of the institution.

CHAPTER 4
INTERNATIONAL AGREEMENTS

The chapter includes International and multilateral agreements of which India is a signatory.

The relevant rules discussed in this chapter include:

1. Convention on Biological Diversity (CBD)
2. Cartagena Protocol on Biosafety
3. Nagoya Protocol

1. Convention on Biological Diversity (CBD)

The Convention on Biological Diversity is a multilateral environmental agreement with 196 state parties. The convention was adopted with an intention of ensuring the conservation of biological diversity, sustainable use of its component, and the fair and equitable sharing of benefits arising from genetic resources. The Convention promotes the cooperation between the Parties to ensure the conservation and sustainable use of biological diversity. The party is required to introduce appropriate procedures for the environmental impact assessment of the proposed projects. Each Contracting Party is directed to take appropriate legislative, administrative or policy measures to provide for the effective participation of contracting parties, particularly developing countries, which provide the genetic resources for such research in biotechnological research activities. In case of imminent or grave danger or damage, originating under its jurisdiction or control, to biological diversity, the Contracting Party is required to notify the potentially affected States of such danger or damage, as well as initiate action to prevent or minimize such danger or damage immediately.

2. Cartagena Protocol on Biosafety

The Cartagena Protocol on Biosafety is a legally binding International agreement with 103 signatories and 173 parties adopted to protect biological diversity from the potential risks of Living modified organisms (LMOs). The Protocol takes a precautionary approach, in accordance with the Principle 15 of the Rio Declaration on Environment and Development. The protocol was installed to contribute to ensuring the safe transfer, handling and use of LMOs that can potentially have an adverse impact on biodiversity by focussing specifically on transboundary movement. The Cartagena Protocol enables the State parties to balance public health against economic benefits. Cartagena Protocol effective since 2003 is a supplement to the Convention of Biological Diversity.

The Protocol requires each state party to take necessary legal, administrative and other measures to implement its obligation under this protocol. The Protocol emphasises the right of the State Party to subject the LMOs to risk assessment prior to their import into the territory. The Protocol also recognises the right of the State Party to set regulations in their accordance for the contained use of the imported LMOs within their territory. The Party of the exporter is required to notify the competent national authority of the Party of import prior to the intentional transboundary movement of a living modified organism. The Party of import is required to acknowledge the receipt of notification within ninety days of receipt. The protocol also recognises that a failure to acknowledge the receipt of notification by the State party shall not imply its consent to an International transboundary movement. In the case of an illegal transboundary movement, the affected Party is allowed to request the Party of origin to dispose of, at its own expense, the LMOs in question by repatriation or destruction, as deemed appropriate in accordance with the Protocol.

3. Nagoya Protocol

Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits was negotiated to further advance the implementation of the third objective of the Convention on Biological Diversity. The protocol provides legal certainty and transparency for both providers and users of genetic resources to ensure access to genetic resources and equitable sharing of benefits. The protocol strives to enhance the contribution of biological diversity to sustainable development and human well-being through promoting the use of genetic resources and strengthening the opportunities for fair and equitable sharing of benefits from their use.

The Protocol requires each state party to take necessary legal, administrative and other measures to ensure fair and equitable sharing of the benefits arising from the utilisation of genetic resources and traditional knowledge associated with genetic resources. To ensure the sovereign rights of the state party over its natural resources, the Protocol mandates the requirement of consent from the Party providing the genetic resources unless stated otherwise by the Party. The protocol also promotes the collaboration and cooperation of the Parties in technical and scientific research and development programmes, including biotechnological research activities, as a means to achieve the objective of this Protocol.

CHAPTER 5
UNATTENDED PROBLEMS AND LEGAL GAPS

1. Ambiguity in circumstances when Deliberate Release shall be approved

Rule 9 under "**Rules for the Manufacture, Use/Import/Export and Storage of Hazardous Microorganisms/Genetically Engineered Organisms or Cells, 1989**" includes guidelines regarding Deliberate and Unintentional Release of GMO into the environment. The rule forbids Deliberate or unintentional transfer of GMOs into the environment with the exception of special cases when deliberate release may be allowed with the approval of GEAC. But the rule fails to explain the circumstances surrounding special cases or what qualifies as a special case. The rule must elaborate what amounts to special cases and the circumstances when the release shall be permitted. This amendment in the legal framework is necessary to prevent the deliberate release of GMOs against the interest of the public by granting its approval as a special case. The rule should be more elaborate and discuss what are the criteria to be fulfilled by the GMO to be eligible for deliberate release. The release of GMOs into the environment can have potentially negative consequences with respect to ecological diversity and balance and therefore a standard guideline is required for evaluating if the GMO can potentially have an adverse impact on the ecosystem and biodiversity.

2. Exclusion of the definition of modern biotechnology

The definition of Biotechnology as defined by "**Rules for the Manufacture, Use/Import/Export and Storage of Hazardous Microorganisms/Genetically Engineered Organisms or Cells, 1989"** is as follows:

> *"Biotechnology" means the application of scientific and engineering principles to the processing of materials by biological agents to produce goods and services.*

This definition is primitive and lacks clarity. Even though India is a signatory to the Cartagena Protocol, it is yet to adopt the definition of modern biotechnology in national regulation, which is stated as follows:

“Modern biotechnology” means the application of:

a. *In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or*
b. *Fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.*

3. Restricted Definition of Environment Pollutants in Environment Protection Act

Environment Pollutants is defined as follows in the **Environment Protection Act**:

"environmental pollutant" means any solid, liquid or gaseous substance present in such concentration as may be, or tend to be, injurious to the environment.

This definition of environmental pollutants is out-of-date and highly restrictive. The definition is restricted to abiotic factors like solid, liquid or gaseous substances which leave out biotic factors. A more inclusive definition for pollutants should be adopted to account for biotic factors such as microorganisms under the EPA.

4. Exemption of unviable GMO under Cartagena Protocol

Cartagena protocol is not inclusive of all genetically engineered organisms and is limited to Living modified organisms (LMOs). LMOs are GMOs that are viable and includes commodities such as grains, soya beans, maize etc. Products such as processed GMOs, pharmaceuticals or other products of gene technologies are exempted by the protocol if they are unable to reproduce.

5. Lack of Comprehensive Liability Regime in Cartagena Protocol

Cartagena Protocol lacks a liability regime to hold the exporting state accountable for the damages caused in the importing state due to LMOs imported from the exporting state. In the absence of a liability regime, the imported states cannot be adequately protected from potential risks of LMOs and force the impacted state to bear the cost of remedy, while the exported state enjoy the profit without taking responsibility for the damages caused by the LMOs.

6. Need to develop guidelines and regulations for emerging gene technologies

Biotechnology is a rapidly evolving field of research that can transform the landscape of agriculture and healthcare technologies. The rapid development of biotechnology and innovations in this field leads to the emergence of new gene technologies which has the potential to improve the quality of life. A multilateral collaboration should formulate global standards to regulate emerging gene technologies. Adoption of such a protocol will contribute to promote responsible research and provide clarity on how the emerging technologies will be dealt with.

REFERENCES

Chapter 1:

1. The Prevention of Cruelty of Animals Act, 1960
2. Breeding of Experiments on Animals (Control and Supervision) Rules, 1998
3. Drug and Cosmetics Act, 1940
4. Right to Information Act, 2005
5. Guidelines for generating pre-clinical data for rDNA vaccines, diagnostics and other biologicals
6. iGEM:Safety/Policies

Chapter 2:

1. General Notes regarding Import Policy
2. Regulation for Import of GM Products 2006-07
3. Directorate General of Foreign Trade | Ministry of Commerce and Industry | Government of India
4. Rules for the Manufacture, Use/Import/Export, and Storage of Hazardous Microorganisms/Genetically Engineered Organisms or Cells, 1989
5. Standard Operating Procedure (SOP) for the Transport of Regulated Genetically Engineered Plant Material
6. Plant Quarantine (Regulation of Import into India) Order, 2003
7. National Biodiversity Authority of India

Chapter 3:

1. Environment Protection Act, 1989 (No. 29 of 1986 dated 23rd May 1986)
2. Rules for the Manufacture, Use/Import/Export and Storage of Hazardous Microorganisms/Genetically Engineered Organisms or Cells, 1989, notified under EPA
3. Biomedical Waste (Management and Handling) Rules, 1998, notified under EPA
4. Biological Diversity Act, 2002 (No. 18 of 2003)
5. Convention on Biological Diversity (CBD)
6. Secretariat of the Convention on Biological Diversity (2000). Cartagena Protocol on Biosafety to the Convention on Biological Diversity: text and annexes. Montreal: Secretariat of the Convention on Biological Diversity.
7. Nagoya Protocol
8. Ahuja V. (2018). Regulation of emerging gene technologies in India. BMC proceedings, 12(Suppl 8), 14. https://doi.org/10.1186/s12919-018-0106-0

Chapter 4:

1. Convention on Biological Diversity (CBD)

2. Secretariat of the Convention on Biological Diversity (2000). Cartagena Protocol on Biosafety to the Convention on Biological Diversity: text and annexes. Montreal: Secretariat of the Convention on Biological Diversity.
3. Nagoya Protocol

Chapter 5:

1. Environment Protection Act, 1989 (No. 29 of 1986 dated 23rd May 1986)
2. Rules for the Manufacture, Use/Import/Export and Storage of Hazardous Microorganisms/Genetically Engineered Organisms or Cells, 1989, notified under EPA
3. Secretariat of the Convention on Biological Diversity (2000). Cartagena Protocol on Biosafety to the Convention on Biological Diversity: text and annexes. Montreal: Secretariat of the Convention on Biological Diversity.
4. Shortcomings of the Cartagena Protocol: resolving the liability loophole at an international level (n.d.) >The Free Library. (2014). https://www.thefreelibrary.com/Shortcomings+of+the+Cartagena+Protocol%3a+resolving+the+liability...-a0203279207
5. Mc Hugan. A. n.d. Problems with the Cartagena Protocol. https://www.asiabiotech.com/10/1012/0684_0687.pdf
6. Padmanabhan. A, Reddy. R, Sharma .S. (2017). Modern Biotechnology and India's governance imperatives. https://carnegieendowment.org/files/CP_311_Padmanabhan_FNL4WEB.pdf